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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,824	02/27/2001	David J Squirrell	1498-119	3738

7590 01/30/2004

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EXAMINER	
STEADMAN, DAVID J	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 01/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/763,824	SQUIRRELL ET AL.	
	Examiner	Art Unit	
	David J Steadman	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-30* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the Application

[1] Claims 1-30 are pending in the application.

[2] Applicants' amendment to the claims, filed February 27, 2001, is acknowledged.

[3] Receipt of information disclosure statements, filed February 27, 2001 and October 16, 2003, is acknowledged.

[4] Applicants' amendment to the specification, filed August 19, 2002, is acknowledged.

[5] Applicants' amendment to the specification, filed April 23, 2003, is acknowledged.

[6] Receipt of a sequence listing in computer readable and paper copy forms, filed August 19, 2002, is acknowledged.

Lack of Unity

[7] Lack of unity is required under 35 U.S.C. 121 and 372. This application contains the following inventions or goups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. Note – for Groups I(a)-(i), II(a)-(i), III(a)-(i), IV(a)-(i), Groups X(a)-(i), Groups XI(a)-(i), Groups XII(a)-(i), and Groups XIII(a)-(i), applicant should elect a single luciferase variant (*e.g.,* Group II(c)) or specific combination of mutations within a single luciferase (*e.g.,* Groups I(a), I(c) and I(i)).

Groups I(a)-I(i), claims 1-5, 7-25, and 28-30, drawn to the special technical feature of a protein variant of *Photinus pyralis* luciferase having increased

thermostability, a nucleic acid encoding therefor, a vector, a cell, a plant, the first claimed method of use, *i.e.,* the use of a protein in a bioluminescent assay, and a kit. Group I(a) recites a mutation at residue 214 of *P. pyralis* luciferase; Group I(b) recites a mutation at residue 232 of *P. pyralis* luciferase; Group I(c) recites a mutation at residue 295 of *P. pyralis* luciferase; Group I(d) recites a mutation at residue 14 of *P. pyralis* luciferase; Group I(e) recites a mutation at residue 35 of *P. pyralis* luciferase; Group I(f) recites a mutation at residue 105 of *P. pyralis* luciferase; Group I(g) recites a mutation at residue 234 of *P. pyralis* luciferase; Group I(h) recites a mutation at residue 420 of *P. pyralis* luciferase; and Group I(i) recites a mutation at residue 310 of *P. pyralis* luciferase.

Groups II(a)-II(i), claims 1-4, 6-9, 11-13, 17-25, and 28-30, drawn to the special technical feature of a protein variant of *Luciola mingrelica* luciferase having increased thermostability, a nucleic acid encoding therefor, a vector, a cell, a plant, the first claimed method of use, *i.e.,* the use of a protein in a bioluminescent assay, and a kit. Group II(a) recites a mutation at residue 216 of *L. mingrelica* luciferase; Group II(b) recites a mutation at residue 234 of *L. mingrelica* luciferase; Group II(c) recites a mutation at residue 297 of *L. mingrelica* luciferase; Group II(d) recites a mutation at residue 16 of *L. mingrelica* luciferase; Group II(e) recites a mutation at residue 37 of *L. mingrelica* luciferase; Group II(f) recites a mutation at residue 106 of *L. mingrelica* luciferase; Group II(g) recites a mutation at residue 236 of *L. mingrelica* luciferase; Group II(h) recites a mutation at residue 422 of *L. mingrelica* luciferase; and Group II(i) recites a mutation at residue 312 of *L. mingrelica* luciferase.

Groups III(a)-III(i), claims 1-4, 6-9, 11-13, 17-25, and 28-30, drawn to the special technical feature of a protein variant of *L. cruciata* luciferase having increased thermostability, a nucleic acid encoding therefor, a vector, a cell, a plant, the first claimed method of use, *i.e.,* the use of a protein in a bioluminescent assay, and a kit. Group III(a) recites a mutation at residue 216 of *L. cruciata* luciferase; Group III(b) recites a mutation at residue 234 of *L. cruciata* luciferase; Group III(c) recites a mutation at residue 297 of *L. cruciata* luciferase; Group III(d) recites a mutation at residue 17 of *L. cruciata* luciferase; Group III(e) recites a mutation at residue 38 of *L. cruciata* luciferase; Group III(f) recites a mutation at residue 107 of *L. cruciata* luciferase; Group III(g) recites a mutation at residue 236 of *L. cruciata* luciferase; Group III(h) recites a mutation at residue 422 of *L. cruciata* luciferase; and Group III(i) recites a mutation at residue 312 of *L. cruciata* luciferase.

Groups IV(a)-IV(i), claims 1-4, 6-9, 11-13, 17-25, and 28-30, drawn to the special technical feature of a protein variant of *L. lateralis* luciferase having increased thermostability, a nucleic acid encoding therefor, a vector, a cell, a plant, the first claimed method of use, *i.e.,* the use of a protein in a bioluminescent assay, and a kit. Group IV(a) recites a mutation at residue 216 of *L. lateralis* luciferase; Group IV(b) recites a mutation at residue 234 of *L. lateralis* luciferase; Group IV(c) recites a mutation at residue 297 of *L. lateralis* luciferase; Group IV(d) recites a mutation at residue 17 of *L. lateralis* luciferase; Group IV(e) recites a mutation at residue 38 of *L. lateralis* luciferase; Group IV(f) recites a mutation at residues 107 and 108 of *L. lateralis* luciferase; Group IV(g) recites a mutation at residue 236 of *L. lateralis* luciferase; Group

IV(h) recites a mutation at residue 422 of *L. lateralis* luciferase; and Group IV(i) recites a mutation at residue 312 of *L. lateralis* luciferase.

Group V, claims 1-3, 21-25, and 28-30, drawn to the special technical feature of a protein variant of *Hotaria paroula* luciferase having increased thermostability, a nucleic acid encoding therefor, a vector, a cell, a plant, the first claimed method of use, *i.e.,* the use of a protein in a bioluminescent assay, and a kit.

Group VI, claims 1-3, 21-25, and 28-30, drawn to the special technical feature of a protein variant of *Pyrophorus plagiophthalamus* luciferase having increased thermostability, a nucleic acid encoding therefor, a vector, a cell, a plant, the first claimed method of use, *i.e.,* the use of a protein in a bioluminescent assay, and a kit.

Group VII, claims 1-3, 21-25, and 28-30, drawn to the special technical feature of a protein variant of *Lampyris noctiluca* luciferase having increased thermostability, a nucleic acid encoding therefor, a vector, a cell, a plant, the first claimed method of use, *i.e.,* the use of a protein in a bioluminescent assay, and a kit.

Group VIII, claims 1-3, 21-25, and 28-30, drawn to the special technical feature of a protein variant of *Pyrocoelia nayako* luciferase having increased thermostability, a nucleic acid encoding therefor, a vector, a cell, a plant, the first claimed method of use, *i.e.,* the use of a protein in a bioluminescent assay, and a kit.

Group IX, claims 1-3, 21-25, and 28-30, drawn to the special technical feature of a protein variant of *Photinus pennsylanvanica* luciferase having increased thermostability, a nucleic acid encoding therefor, a vector, a cell, a plant, the first claimed method of use, *i.e.,* the use of a protein in a bioluminescent assay, and a kit.

Groups X(a)-X(i), claim 26, drawn to the special technical feature of a plant comprising cells containing a vector encoding a protein variant of *Photinus pyralis* luciferase having increased thermostability, a nucleic acid encoding therefor, a vector, a cell, a plant, the first claimed method of use, *i.e.,* the use of a protein in a bioluminescent assay, and a kit. Group X(a) recites a mutation at residue 214 of *P. pyralis* luciferase; Group X(b) recites a mutation at residue 232 of *P. pyralis* luciferase; Group X(c) recites a mutation at residue 295 of *P. pyralis* luciferase; Group X(d) recites a mutation at residue 14 of *P. pyralis* luciferase; Group X(e) recites a mutation at residue 35 of *P. pyralis* luciferase; Group X(f) recites a mutation at residue 105 of *P. pyralis* luciferase; Group X(g) recites a mutation at residue 234 of *P. pyralis* luciferase; Group X(h) recites a mutation at residue 420 of *P. pyralis* luciferase; and Group X(i) recites a mutation at residue 310 of *P. pyralis* luciferase.

Groups XI(a)-XI(i), claim 26, drawn to the special technical feature of a plant comprising cells containing a vector encoding a protein variant of *Luciola mingrelica* luciferase having increased thermostability, a nucleic acid encoding therefor, a vector, a cell, a plant, the first claimed method of use, *i.e.,* the use of a protein in a bioluminescent assay, and a kit. Group XI(a) recites a mutation at residue 216 of *L. mingrelica* luciferase; Group XI(b) recites a mutation at residue 234 of *L. mingrelica* luciferase; Group XI(c) recites a mutation at residue 297 of *L. mingrelica* luciferase; Group XI(d) recites a mutation at residue 16 of *L. mingrelica* luciferase; Group XI(e) recites a mutation at residue 37 of *L. mingrelica* luciferase; Group XI(f) recites a mutation at residue 106 of *L. mingrelica* luciferase; Group XI(g) recites a mutation at

residue 236 of *L. mingrelica* luciferase; Group XI(h) recites a mutation at residue 422 of *L. mingrelica* luciferase; and Group XI(i) recites a mutation at residue 312 of *L. mingrelica* luciferase.

Groups XII(a)-XII(i), claim 26, drawn to the special technical feature of a plant comprising cells containing a vector encoding a protein variant of *L. cruciata* luciferase having increased thermostability, a nucleic acid encoding therefor, a vector, a cell, a plant, the first claimed method of use, *i.e.,* the use of a protein in a bioluminescent assay, and a kit. Group XII(a) recites a mutation at residue 216 of *L. cruciata* luciferase; Group XII(b) recites a mutation at residue 234 of *L. cruciata* luciferase; Group XII(c) recites a mutation at residue 297 of *L. cruciata* luciferase; Group XII(d) recites a mutation at residue 17 of *L. cruciata* luciferase; Group XII(e) recites a mutation at residue 38 of *L. cruciata* luciferase; Group XII(f) recites a mutation at residue 107 of *L. cruciata* luciferase; Group XII(g) recites a mutation at residue 236 of *L. cruciata* luciferase; Group XII(h) recites a mutation at residue 422 of *L. cruciata* luciferase; and Group XII(i) recites a mutation at residue 312 of *L. cruciata* luciferase.

Groups XIII(a)-XIII(i), claim 26, drawn to the special technical feature of a plant comprising cells containing a vector encoding a protein variant of *L. lateralis* luciferase having increased thermostability, a nucleic acid encoding therefor, a vector, a cell, a plant, the first claimed method of use, *i.e.,* the use of a protein in a bioluminescent assay, and a kit. Group XIII(a) recites a mutation at residue 216 of *L. lateralis* luciferase; Group XIII(b) recites a mutation at residue 234 of *L. lateralis* luciferase; Group XIII(c) recites a mutation at residue 297 of *L. lateralis* luciferase; Group XIII(d)

recites a mutation at residue 17 of *L. lateralis* luciferase; Group XIII(e) recites a mutation at residue 38 of *L. lateralis* luciferase; Group XIII(f) recites a mutation at residues 107 and 108 of *L. lateralis* luciferase; Group XIII(g) recites a mutation at residue 236 of *L. lateralis* luciferase; Group XIII(h) recites a mutation at residue 422 of *L. lateralis* luciferase; and Group XIII(i) recites a mutation at residue 312 of *L. lateralis* luciferase.

Group XIV, claim 26, drawn to the special technical feature of a plant comprising cells containing a vector encoding a protein variant of *Hotaria paroula* luciferase having increased thermostability, a nucleic acid encoding therefor, a vector, a cell, a plant, the first claimed method of use, *i.e.,* the use of a protein in a bioluminescent assay, and a kit.

Group XV, claim 26, drawn to the special technical feature of a plant comprising cells containing a vector encoding a protein variant of *Pyrophorus plagiophthalamus* luciferase having increased thermostability, a nucleic acid encoding therefor, a vector, a cell, a plant, the first claimed method of use, *i.e.,* the use of a protein in a bioluminescent assay, and a kit.

Group XVI, claim 26, drawn to the special technical feature of a plant comprising cells containing a vector encoding a protein variant of *Lampyris noctiluca* luciferase having increased thermostability, a nucleic acid encoding therefor, a vector, a cell, a plant, the first claimed method of use, *i.e.,* the use of a protein in a bioluminescent assay, and a kit.

Group XVII, claim 26, drawn to the special technical feature of a plant comprising cells containing a vector encoding a protein variant of *Pyrocoelia nayako* luciferase having increased thermostability, a nucleic acid encoding therefor, a vector, a cell, a plant, the first claimed method of use, *i.e.,* the use of a protein in a bioluminescent assay, and a kit.

Group XVIII, claim 26, drawn to the special technical feature of a plant comprising cells containing a vector encoding a protein variant of *Photinus pennsylanvanica* luciferase having increased thermostability, a nucleic acid encoding therefor, a vector, a cell, a plant, the first claimed method of use, *i.e.,* the use of a protein in a bioluminescent assay, and a kit.

[8] The inventions listed as Groups I-XVIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reason(s):

According to PCT Rule 13.2 and to the guidelines in Section (f)(i)(B)(1) of Annex B of the PCT Administrative Instructions, all alternatives of a Markush Group must have a common structure. Although the luciferase variants of Groups I-IX and the luciferase variants encoded by the vectors contained in the cells of the plant of Groups X-XVIII share a common property or activity, the polypeptides are not regarded as being of similar nature because all alternatives do not share a common structure.

According to PCT Rule 13.2, unity of invention exists only when there is a shared same or corresponding special technical feature among the claimed inventions. The special technical feature of Groups I-IX is a polypeptide variant, while the special

technical feature of Groups X-XVIII is a plant. The polypeptide variants of Groups I-IX have a special technical feature that is not shared by the plants of Groups X-XVIII.

[9] Claims 1-9, 11-13, 17-26, and 28-30 will be examined only to the extent the claims read on the elected subject matter.

[10] Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

[11] Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Friday from 7:00 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX number for submission of official papers to Group 1600 is (703) 308-4242. Draft or informal FAX communications should be directed to (703) 746-5078. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman, Ph.D.
Patent Examiner
Art Unit 1652

01-23-04
DAVID STEADMAN
PATENT EXAMINER